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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/035,420

10/25/2001

Sidney N. Wolfe

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02/15/2008

NOVARTIS VACCINES AND DIAGNOSTICS INC

INTELLECTUAL PROPERTY - R338

PO BOX 8097

EMERYVILLE, CA 94662-8097

EXAMINER

SEHARASEYON, JEGATHESAN

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

02/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/035,420	WOLFE ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9, 13-17, 19, 20, 26-43 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9, 13-17, 19, 20, 26-43 and 45-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) <input type="checkbox"/> Notice of Informal Patent Application
6) <input type="checkbox"/> Other: _____. |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/10/2007 has been entered. An action on the RCE follows.

2. Claims 5-19, 13-17, 19, 20, 26-43, and 45-49 remain in the application. Claims 5, 13, 19 and 42 have been amended. Therefore, claims 5-19, 13-17, 19, 20, 26-43, and 45-49 are pending and examined.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph, withdrawn

4. The rejection of claims 5-19, 13-17, 19, 20, 26-43, and 45-49 under 35 USC § 112, first paragraph, is withdrawn because Applicant has amended claims 5, 13, 19 and 42 to remove the limitation "free of glycerol and polyethylene glycol polymers" which was previously deemed to be new matter in the Office Action dated 11/27/2006.

5. Rejection necessitated by Applicants amendments.

Claim Rejections - 35 USC § 103, (re applied)

6. The rejection of claims 5-9, 13-17, 19, 20, 26-43, and 45-49 under 35 USC § 103 as being obvious over Dorin et al. (U. S. Patent No. 5, 814, 485) in view of Hershenson et al. (U. S. Patent No. 5, 004, 605) and further in view of The Merck Index

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(1989) is re applied because Applicant has amended the claims to remove "free of glycerol and polyethylene glycol polymers" which previously overcame the prior art of record. This rejection has been made of record previously in the Office Actions dated 11/8/2004, 6/27/2005, 4/13/2006 and 11/27/2006. In addition, the Office in the Office Action dated 11/27/2006 had indicated that if Applicant amends the claims to remove the new matter (free of glycerol and polyethylene glycol polymers), the art rejection of record will be reinstated.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7a. Claims 5-9, 13, 14-17, 19, 20, 26, 27, 28, 31, 32, 33, 35-40, 42, 43, 45, 46, 47 and 48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9, 31-35, 61-63, 68, 69, 70, 75-77 of

U.S. Patent No. 6,887, 462. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and the allowed patent claim a pharmaceutical composition having a pH of about 3.0 to about 5.0 and comprising interferon-beta (IFN- β). The compositions also do not preclude an ionic strength less than 20mM. SEQ ID NO: 1 discloses human IFN- β and SEQ ID NO: 2 discloses human IFN- β ser-17 variant. Therefore, claims 5-9, 13, 14-17, 19, 20, 26, 27, 28, 31, 32, 33, 35-40, 42, 43, 45, 46, 47 and 48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9, 31-35, 61-63, 68, 69, 70, 75-77 of U.S. Patent No. 6,887, 462.

Conclusion

8. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS

February 10th, 2008.

/Jegatheesan Seharaseyon/
Primary Examiner, Art Unit 1647